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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,414	07/12/2006	Jan O. Aasly	07039-784US1	7585

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,414	AASLY ET AL.	
	Examiner	Art Unit	
	JOANNE HAMA	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-3,10 and 11* is/are allowed.

6)☒ Claim(s) *4 and 5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final Action of March 18, 2008 on June 18, 2008. Claims 6-9 are cancelled. Claims 1, 2, 4, 5 are amended. Claims 10, 11 are new.

Claims 1-5, 10, 11 are under consideration.

Specification

Applicant's arguments, see pages 4-5 of Applicant's response, filed June 18, 2008, with respect to the objection to the specification have been fully considered and are persuasive. Applicant indicates that a substitute sequence listing that includes the polypeptide sequences shown in Figure 5 as well as the primer sequences show on page 5 has been filed. The objection of the specification has been withdrawn.

Withdrawn Rejections/Objection

Claim Objections

The objection of claims for being a substantial duplicate of claim 4 is withdrawn as claim 6 is cancelled.

35 USC § 112, 2nd parag.

Applicant's arguments, see page 5 of Applicant's response, filed June 18, 2008, with respect to the rejection of claims 1-6 as being rejected for claiming a polynucleotide sequence that comprises an "X" as a nucleotide to be substituted have been fully

considered and are persuasive. Applicant indicates that claim 1 has been amended to address this issue. This is found persuasive and the rejection of claims 1-5 has been withdrawn. It is noted that the rejection of claim 6 is withdrawn as the claim is cancelled.

Applicant's arguments, see page 5 of Applicant's response, filed June 18, 2008, with respect to the rejection of claim 5 as being rejected for using a probe of claim 5 have been fully considered and are persuasive. Applicant indicates that claim 5 has been amended such that the method of claim 5 depends on the probe of claim 10. The rejection of claim 5 with respect to this issue is withdrawn.

35 USC § 102

Applicant's arguments, see page 5-6 of Applicant's response, filed June 18, 2008, with respect to the rejection of claims 4, 6 as being anticipated by Maiti et al (US Patent 6,420,547) have been fully considered and are persuasive. Applicant indicates that claim 4 has been amended to "at least 18 consecutive" nucleotides. The rejection of claim 4 has been withdrawn. It is noted that the rejection of claim 6 is withdrawn as the claim is cancelled.

New/Maintained Rejections

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 5 is newly rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected in modified form under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's amendment raises a new ground of rejection. Response to Applicant's amendment, June 18, 2008 will be addressed after then new ground of rejection.

Claim 5 provides for the use of a DNA primer or probe, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Applicant's arguments, see page 5 of Applicant's response, filed June 18, 2008, with respect to the rejection of claim 5 as being rejected for not reciting an essential method step have been fully considered but are not persuasive. Applicant indicates that claim 5 has been amended to recite the essential step and to indicate the result that the artisan is looking for. In response, this is not persuasive because the step of "using" the DNA primer or probe does not indicate how the probe is used to indicate parkinsonian inheritance. The rejection as it applies to this issue remains.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Spytek et al., WO 02/081627, published October 17, 2002.

A sequence search of 27 consecutive nucleotides of SEQ ID NO. 2 was carried out. The sequence search indicates that RTQ-PCR probe #3 of human protein NOV19 is identical to nucleotides 6984 to 7010 SEQ ID NO. 2 (see attached).

Thus, claim 4 is rejected.

Conclusion

Claims 1-3, 10, 11 are allowable.

Claims 4, 5 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Mondays, Tuesdays, Thursdays, and Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Joanne Hama/
Art Unit 1632

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RESULT 3
ABX17598
ID   ABX17598 standard; DNA; 27 BP.
XX
AC   ABX17598;
XX
DT   05-FEB-2003  (first entry)
XX
DE   RTQ-PCR probe #3 for human protein NOV19.
XX
KW   Human; ss; NOVX; adrenoleukodystrophy; haemophilia; stoke; VHL; PCR;
KW   congenital adrenal hyperplasia; haemophilia; hypercoagulation;
KW   idiopathic thrombocytopaenic purpura; autoimmune disease; allergy;
KW   immunodeficiencies; transplantation; Von Hippel-Lindau syndrome;
KW   Alzheimer's disease; tuburous sclerosis; Parkinson's disease; epilepsy;
KW   Huntington's disease; cerebral palsy; Lesch-Nyhan syndrome; pain;
KW   multiple sclerosis; ataxia-telangiectasia; leukodystrophy; anxiety;
KW   behavioural disorder; addiction; neuroprotection; diabetes; ARDS;
KW   renal artery stenosis; interstitial nephritis; glomerulonephritis;
KW   polycystic kidney disease; systemic lupus erythematosus; IgA; probe;
KW   renal tubular acidosis; immunoglobulin A nephropathy; hypercalcaemia;
KW   cirrhosis; transplantation; asthma; emphysema; scleroderma; GVHD;
KW   adult respiratory distress syndrome; graft versus host disease;
KW   lymphedema; fertility; pancreatitis; obesity; haemophilia; ulcer;
KW   anaemia; cancer; trauma; regeneration; infection; RTQ-PCR;
KW   real-time quantitative PCR.
XX
OS   Homo sapiens.
XX
PN   WO200281629-A2.
XX
PD   17-OCT-2002.
XX
PF   03-APR-2002; 2002WO-US010522.
XX
PR   03-APR-2001; 2001US-0281086P.
PR   03-APR-2001; 2001US-0281136P.
PR   05-APR-2001; 2001US-0281863P.
PR   05-APR-2001; 2001US-0281906P.
PR   06-APR-2001; 2001US-0282020P.
PR   10-APR-2001; 2001US-0282934P.
PR   12-APR-2001; 2001US-0283512P.
PR   19-APR-2001; 2001US-0285325P.
PR   23-APR-2001; 2001US-0285890P.
PR   24-APR-2001; 2001US-0286068P.
PR   25-APR-2001; 2001US-0286292P.
PR   27-APR-2001; 2001US-0287213P.
PR   02-MAY-2001; 2001US-0288257P.
PR   12-MAY-2001; 2001US-0291134P.
PR   17-MAY-2001; 2001US-0291725P.
PR   31-MAY-2001; 2001US-0294771P.
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PR 08-JUN-2001; 2001US-0296965P.
PR 18-JUN-2001; 2001US-0299128P.
PR 12-JUL-2001; 2001US-0305063P.
PR 14-NOV-2001; 2001US-0332780P.
PR 04-JAN-2002; 2002US-0345221P.
PR 02-APR-2002; 2002US-00115482.
XX
PA (CURA-) CURAGEN CORP.
XX
PI Spytek KA, Li L, Edinger SR, Ellerman K, Stone DJ, Malyankar UM;
PI Shimkets RA, Guo X, Anderson DW, Patturajan M, Berghs C, Gerlach V;
PI Taupier RJ, Pena CEA, Padigaru M, Liu Y, Burgess CE, Miller CE;
PI Gusev VY, Kekuda R, Gorman L, Zerhusen BD, Baumgartner JC;
PI Tchernev VT, Vernet CAM, Smithson G, Heyes MP, Shenoy SG, Liu X;
PI Gangolli EA;
XX
DR WPI; 2003-046863/04.
XX
PT New polypeptides, designated NOVX polypeptides, useful for treating
PT hemophilia, idiopathic thrombocytopenic purpura, autoimmune disease,
PT allergies, transplantation, Alzheimer's disease and stroke.
XX
PS Example C; Page 265; 320pp; English.
XX
CC The invention relates to an isolated NOVX polypeptide selected from
NOV1-
CC NOV27 polypeptides, a mature form of NOVX, a variant of NOVX or a
CC fragment of NOVX. Also included are determining the presence or amount
of
CC NOVX in a sample (by using an antibody that immunospecifically bind to
CC the polypeptide), determining the presence of or predisposition to
CC disease associated with altered levels of NOVX in a first mammalian
CC subject, identifying a potential therapeutic agent for use in the
CC treatment of pathology related to aberrant expression of physiological
CC interactions of NOVX, screening for a modulator of activity or of
latency
CC or predisposition to a pathology associated with NOVX, the nucleic acid
CC encoding NOVX, vectors and host cells. NOVX is useful for identifying an
CC agent (a cellular receptor or downstream effector) that binds to NOVX.
CC NOVX and NOVX nucleic acids are useful for treating or preventing NOVX-
CC associated disorders in humans, and in the manufacture of a medicament
CC for treating a NOVX related disease human disease e.g.
CC adrenoleukodystrophy, congenital adrenal hyperplasia, haemophilia,
CC hypercoagulation, idiopathic thrombocytopaenic purpura, autoimmune
CC disease, allergies, immunodeficiencies, transplantation, Von Hippel-
CC Lindau (VHL) syndrome, Alzheimer's disease, stroke, tuburous sclerosis,
CC Parkinson's disease, Huntington's disease, cerebral palsy, epilepsy,
CC Lesch-Nyhan syndrome, multiple sclerosis, ataxia-telangiectasia,
CC leukodystrophies, behavioural disorders, addiction, anxiety, pain,
CC neuroprotection, diabetes, renal artery stenosis, interstitial
nephritis,
CC glomerulonephritis, polycystic kidney disease, systemic lupus
CC erythematosus, renal tubular acidosis, immunoglobulin (Ig) A
nephropathy,

```
CC   hypercalcaemia, cirrhosis, transplantation, asthma, emphysema,
CC   scleroderma, adult respiratory distress syndrome (ARDS), graft versus
CC   host disease (GVHD), lymphedema, fertility, pancreatitis, obesity,
CC   haemophilia, ulcers, anaemia, cancer, trauma, regeneration, and viral,
CC   bacterial or parasitic infections. The present sequence is a real-time
CC   quantitative (RTQ)-PCR probe used to determine the tissue specific
CC   expression of a NOVX mRNA
XX
SQ   Sequence 27 BP; 9 A; 6 C; 3 G; 9 T; 0 U; 0 Other;

  Query Match             0.4%;  Score 27;  DB 8;  Length 27;
  Score over Length       100.0%;
  Best Local Similarity   100.0%;  Pred. No. 1.8e+04;
  Matches   27;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy       6984 TGATTTCACCATTCAGAAACTCATTGA 7010
              |||||||||||||||||||||||||||
Db          1 TGATTTCACCATTCAGAAACTCATTGA 27
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